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ATTORNEY DOCKET NO. 22000.0110U2 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
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CAPDEVILA et al.) Group Art Unit: 1636
)
Serial No. 09/942,429) Examiner: Vogel, N.
)
Filed: August 29, 2001)
) Confirmation No.: 7467
For: COMPOSITIONS AND METHODS)
RELATING TO HYPERTENSION)

ELECTION UNDER RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C. Customer Number 36339

Sir:

This is in response to the Office Action dated September 9, 2003, wherein restriction of the claims of the above-identified application is required. A Request for Extension of Time is included herewith. The Office Action requires restriction to one of twenty-two (22) groups of claims.

According to the Office Action, the inventions of Groups I-XXII represent distinct inventions. The Office Action also states that the application contains claims directed to patentably distinct species of the claimed invention. Further stated is that claim 39 is a generic claim and applicants are required under 35 U.S.C. § 121 to elect a single disclosed for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

As required in response to this Action, applicants provisionally elect Group XXII (claims 39-43), with traverse. Applicants also provisionally elect a method of identifying a subject having an increased susceptibility for developing hypertension comprising detecting a mutant Cyp4A11 which is Cyp4A11/W126→R. Claims 39 and 40 are readable upon the elected species. Applicants acknowledge that, upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species.

The Examiner has requested that the applicants elect a specific "species."

Applicants traverse this election of species requirement for the following reasons. As discussed in the 37 C.F.R. § 1.141(a), an application may claim a reasonable number of species within a claimed genus as long as at least one genus claim encompassing all of the species is patentable. The Examiner has indicated that detection of a *specific* mutation of Cyp4A11 must be elected. Applicants assert that this is not an appropriate application of the 37 C.F.R. § 1.141, which is aimed at situations where there are unreasonable numbers of species claimed. The present situation is not a situation where the applicants are claiming a genus of compounds, for example, a set of 1000 different nucleic acid molecules, and also claiming each of the encompassed species separately, which would be an appropriate application of the election of species requirement.

Rather, applicants have claimed a method having a defined number of steps, and then claimed a reasonable number of dependent variations on that method. Applicants are not required in the present application to elect a species when applicants have not claimed an unreasonable number of species.

Also, applicants respectfully request that the entire restriction requirement be reconsidered because the Examiner has not shown that a serious burden would be required to examine all the claims. M.P.E.P. § 803 provides:

If the search and examination of an entire application can be made without serious burden, the Examiner <u>must</u> examine it on the merits, even though it includes claims to distinct or independent inventions. (*Emphasis added*.)

Thus, for a restriction requirement to be proper, the Examiner must satisfy the following two criteria: (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden.

Applicants respectfully assert that the Examiner has not shown that the second requirement has been met, on the basis that the Examiner has not shown that it would be a serious burden to search and examine all of the groups together. This is particularly true for Groups I-XII and XIX-XXII, which are all in the same class and can readily be searched together. Similarly, Group XIII-XVIII are all in the same class and can be readily searched together. Therefore, applicants believe it would not be a serious burden on the Examiner to examine all of the claims of Groups I-XII and IXX-XXII or all of the claims of Groups XIII-XVIII together.

For the reasons stated above, applicants respectfully assert that restriction of the claims as set forth by the Examiner would be contrary to promoting efficiency, economy and expediency in the Patent Office and further point out that restriction by the Examiner is discretionary (M.P.E.P. § 803.01). Thus, applicants respectfully request that all of the claims of this application be examined together. Consequently, reconsideration and

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modification or withdrawal of the restriction requirement is requested.

Applicants also wish to remind the Examiner of the guidelines for rejoinder of claims as set forth in M.P.E.P. § 821.04, as they apply to the pending claims of the instant application.

A Request for Extension of Time and Credit Card Form PTO-2038 authorizing payment in the amount of \$475.00, are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

Lizette M. Fernandez, Ph.D

Registration No. 46,694

NEEDLE & ROSENBERG, P.C.

Customer Number: 36339

(404) 688-0770

(404) 688-9880 (fax)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450, on the date shown below.

Date\

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